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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/663,825

09/16/2003

Gunter Rauchschalbe

CH-7768/LeA 36,070

2689

34947

7590

05/10/2004

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PATENT DEPARTMENT
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EXAMINER

SHIAO, REI TSANG

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,825	RAUCHSCHWALBE ET AL.	
	Examiner	Art Unit	
	Robert Shiao	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on application filed on 09/16, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>0504</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Application claims the benefit of the foreign application:
GERMANY 10243027.6, filed on September 17, 2002.
2. Claims 1-7 are pending in the case.

Election/Restriction

3. The group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. For these reasons provided below, restriction to one of the following Groups is required under 35 U.S.C. 121, wherein an Group is a set of patentably distinct inventions of a broad statutory category (e.g. Compounds, Methods of Use, Methods of Making, etc.):

- I. Claims 1-6, drawn to a process of preparing 2-phenylbenzimidazole-5-susulphonic acid, classified in classes 548, numerous subclasses.
- II. Claims 7, drawn to a process of preparing cosmetic compositions, classified in classes 424, numerous subclasses.

An election of any one of Groups I-II is required. Should applicant traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C 103(a) of the other.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventors must be amended in compliance with 37C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37CFR 1.17(i).

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise

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caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Rationale Establishing Patentable Distinctiveness Within Each Group

Each Invention Set listed above is directed to or involves the use or making of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of the other inventions, i.e. they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

Groups I-II are independent and distinct processes, because starting

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materials (i.e., carriers), reaction conditions or processes, each group differ in elements, bonding arrangement and chemical property to such an extent that a reference anticipating compounds of any one group would not render another group obvious.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In addition, because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

Responses to Election/Restriction

4. During a telephone conversation with Godfried R. Akorli on February 3, 2004, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-6. Affirmation of this election must be made by applicant in replying to this Office action. Claim 7 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter "an agent which comprises 1.0 to 3.0 mol of SO₂", which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, see claim 1, line 6.

7. Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for processes of making using agents Na₂HSO₃, Na₂S₂O₅ or Na₂SO₃ as reactants, does not reasonably provide enablement for processes using an agent other than Na₂HSO₃, Na₂S₂O₅ or Na₂SO₃. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, see claim 1, line 6. Incorporation of the named agents into the claims would obviate the rejection, see page 5, line 3.

Claim 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

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one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claims are drawn to processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0 mol of SO₂ without limitation.

2) State of the prior art.

The reference Heywang et al. US 6,440,401, does not indicate which compounds of instant compounds may be useful in the claimed invention. Heywang et al. et al. '401 is pertaining to 2-phenyl-benzimidazolesulfonic acids as UV-B-filters.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The claimed processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0 mol of

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SO₂ without limitation, encompasses a vast number of methods. Applicant's specification does not enable the public to prepare such a numerous processes of making 2-phenylbenzimidazole-5-susulphonic acid by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The claimed processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0 mol of SO₂ without limitation, remains highly unpredictable, see claim 1, line 6. Different types of processes of making "processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0 mol of SO₂ without limitation", require various experimental procedures and without guidance that is applicable to all possible "processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0 mol of SO₂ without limitation", there would be little predictability in the scope of claimed methods.

5) Amount of direction and guidance provided by the inventor.

The genus of the claimed processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0 mol of SO₂ without limitation, encompasses a vast number of processes. Applicant's limited guidance does not enable the public to prepare such a numerous amount of "processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0 mol of SO₂ without limitation" in the specification. There is no enablement for processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0

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mol of SO₂ without limitation, i.e., an agent other than Na₂HSO₃, Na₂S₂O₅ or Na₂SO₃ (i.e., K₂HSO₃), many of which are neither enabled nor supported in the specification.

6) Existence of working examples.

The genus of claimed "processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0 mol of SO₂ without limitation", encompasses a vast number of processes. Applicant's limited working examples do not enable the public to prepare such a "processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0 mol of SO₂ without limitation" in the specification. Applicants claim "processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0 mol of SO₂ without limitation", however, the specification provides only limited examples of the instant compounds.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0 mol of SO₂ without limitation".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to

perform in order to obtain "processes of making 2-phenylbenzimidazole-5-susulphonic acid using an agent comprises 1.0 to 3.0 mol of SO₂ without limitation" as claimed.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975. Incorporation of the named agents into the claims would obviate the rejection, see page 5, line 3.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 2 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Rauchschalbe et al. copending application No. 10/663,827. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim a process of making 3,4-diaminobenzenesulphonic acid by sulphonation (i.e., using sulphuric acid) of 1,2-diaminobenzene and this process is found in the pages 3- 5 of the instant application.

Rauchschalbe et al. claim a process of making 3,4-diaminobenzene-sulphonic acid by reacting 1,2-diaminobenzene with sulphuric acid.

The difference between the instant claim and Rauchschalbe et al. is that the instant claim silence use of sulphuric acid.

One having ordinary skill in the art would find the instant claims prima facie obvious **because** one would be motivated to employ the processes of Rauchschalbe et al. to obtain a process of instant claim, wherein a process of making 3,4-diaminobenzene-sulphonic acid is by sulphonation (i.e., using sulphuric acid) of 1,2-diaminobenzene .

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The motivation to make the claimed compounds derives from the expectation that the instant claimed processes would possess similar yields from the known Rauchschalbeet et al. processes to that which is claimed in the reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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for

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626



Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

May 6, 2004